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Using Qualified Data to Document an Observed Release

Office of Emergency and Remedial Response
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Quick Reference Fact Sheet

Abstract

Data validation checks the accuracy of analytical data, and qualifies results that fall outside performance criteria of the Contract Laboratory Program (CLP). Results qualified with a "J" are estimated concentrations that may be biased, but may be used to determine an observed release in Hazard Ranking System (HRS) evaluation. This fact sheet explains the conditions for use of "J"-qualified data, and introduces factors which compensate for variability and enable their use in HRS evaluation.

Why Qualify Data?

Chemical concentration data for environmental decision-making are generated using analytical methods. EPA analytical chemistry methods are designed to provide the definitive analyte identification and quantitation needed to establish an observed release under the Hazard Ranking System (HRS). Routine operational variations in sampling and analysis inevitably introduce a degree of error into the analytical data. Data validation checks the usability of the analytical data for HRS evaluation and identifies the error (bias) present. The validation process qualifies the biased data. Certain types of qualified data for release and background samples may be used to determine an observed release.

EPA Data Qualifiers

EPA analytical methods (e.g., SW-846 and Contract Laboratory Program [CLP]) introduce a number of Quality Assurance/Quality Control (QA/QC) mechanisms during the course of sample analysis to measure qualitative and quantitative accuracy.[3,4,8,9] Such mechanisms include matrix spikes, matrix spike duplicates, laboratory control samples, surrogates, blanks, laboratory duplicates, and quarterly blind performance evaluation (PE) samples. Surrogates and spikes are chemically similar to the analytes of interest and thus behave similarly during the analytical process. They are introduced or "spiked" at a known concentration into the field samples before analysis. Comparison of the known concentrations of the surrogates and spikes with their analytical results measures accuracy, and may indicate bias caused by interferences from the sample medium (matrix effect).[1,2,9] Laboratory control samples contain known concentrations of target analytes, and are analyzed in the same batch as field samples. Their results are used to measure laboratory accuracy. Blanks are analyzed to detect any extraneous contamination introduced either in the field or in the laboratory. Laboratory duplicates consist of one sample that undergoes two separate analyses; the results are compared to determine laboratory precision. Quarterly blind PE samples also evaluate lab precision.

CLP and other EPA analytical methods include specifications for acceptable identification, and minimum and maximum percent recovery of the target analytes and QA/QC compounds. Data are validated according to guidelines which set performance criteria for instrument calibration, analyte identification, and identification and recovery of the QA/QC compounds.[3,4,9] The *National Functional Guidelines for Data Review* used in EPA validation were designed for data generated under the CLP organic and inorganic analytical protocols.[1,2,3,4] The guidelines do not preclude the validation of field and non-CLP data; many EPA Regions have adapted the *National Functional Guidelines for Data Review* to validate non-CLF data. Data which do not meet the

guidelines' performance criteria are qualified to indicate bias or QC deficiencies. The data validation report usually explains why the data were qualified and indicates the direction of bias when it can be determined. Most EPA validation guidelines use the data qualifiers presented below.[1,2] (Other data qualifiers besides these are in use; always check the validation report for the exact list of qualifiers and their meanings.)

- **"U" qualifier** -- the analyte was analyzed for, but was not detected above the reported sample quantitation limit. For practical purposes, "U" means "not detected"; the result is usable for characterizing background concentrations for HRS evaluation.[5]

- **"J" qualifier** -- the analyte was positively identified; the associated numerical value is the approximate concentration of the analyte in the sample. "J" data are biased, but provide definitive analyte identification, and are usually reliable. They may be used to determine an observed release under conditions specified later in this fact sheet.[5]

- **"N" qualifier** -- the analysis indicates the presence of an analyte for which there is presumptive evidence to make a "tentative identification." "N"data are not sufficiently definitive for HRS evaluation.

- **"NJ" qualifier** -- the analysis indicates the presence of an analyte that has been "tentatively identified" and the associated numerical value represents its approximate concentration. "NJ" data are not sufficiently definitive for HRS evaluation.

- **"UJ" qualifier** -- the analysis was not detected above the reported sample quantitation limit. However, the reported quantitation limit is approximate and may or may not represent the actual limit of quantitation necessary to accurately and precisely measure the analyte in the sample. "UJ" non-detects are not definite; the analyte may be present. The result can be used to document non-detects in background samples under certain conditions.

- **"R" qualifier** -- the sample results are rejected due to serious deficiencies in the ability to analyze the sample and meet quality control criteria. The presence or absence of the analyte cannot be verified. EPA does not use "R" data because they are considered unreliable.[5]

Validated data that are not qualified are unbiased, and can be used at their reported values for HRS evaluation.

Criteria for Determining an Observed Release with Chemical Data

Chemical data demonstrate an observed release when all of the following are true:

1. The release of a hazardous substance is at least partially attributable to the site under investigation.

2. The release sample concentration is greater than or equal to the appropriate detection limit (e.g., sample quantitation limit [SQL]).

3. If background levels are below detection limits, the release sample concentration must be greater than its detection limit, or, if background levels are greater than or equal to detection limits, the release sample concentration must be at least three times the background concentration.[7]

Direction of Bias In "J"-Qualified Data

It is important to understand the bias associated with "J"-qualified data when using them for HRS evaluation. "J" data may have high, low, or indeterminate bias. A low bias means that the reported concentration is most likely an underestimate of the true concentration. For example, data may be biased low when sample holding times for volatile organic compounds (VOCs) are exceeded or when the recovery of QA/QC compounds is significantly less than the true amount originally introduced into the sample. A high bias means that the reported concentration is most likely an overestimate of the true concentration. A bias is indeterminate when it is impossible to ascertain whether the concentration is an overestimate or an underestimate. For example, an indeterminate bias could result when matrix effects obscure QA/QC compounds.

Qualified Data and Direction of Bias

Qualified data may be used when it can be demonstrated that the data meet the HRS rule for determining an observed release despite the bias in the reported concentrations. This condition depends on the direction of bias: low bias data may be used for release samples, and high bias data may be used for background samples. Low bias release samples are underestimates of true concentration. Underestimated release concentrations that still meet the HRS criteria (e.g., they are still three times background level) clearly establish an observed release. High bias background samples are overestimates of background level. If the concentration of unbiased release samples still significantly exceeds an overestimated background level according to HRS criteria, an observed release is clearly established. Similarly, an observed release is established when low bias release concentrations significantly exceed high bias background concentrations according to the HRS criteria.

These scenarios show that low bias "J-"qualified data may be used for release samples at their reported concentrations, and that high bias "J-"qualified data may be used for background samples at their reported concentrations.

High bias release samples may not be used at their reported concentrations because they are an overestimate of true concentration; the true concentration might be less than the HRS criteria for an observed release. The reported concentration for low bias background concentrations may not be compared to release samples because it is most likely an underestimate of background level; the release sample concentration might not significantly exceed the background concentration. However, high bias release data and low bias background data may be used with factors which compensate for the variability in the data. The factors will enable these types of biased data to meet HRS criteria for determining an observed release.

Factors for Biased Data: Tables 1 through 4 (pages 6-13) present analyte-specific factors to address the uncertainty when determining an observed release using high bias release data and low bias background data. The factors are derived from percent recoveries of matrix spikes, surrogates, and laboratory control samples in the CLP Analytical Results Database (CARD) from January 1993 to March 1994.

The range of CARD data for each analyte includes 95 percent of all percent recoveries. Discarding outliers left 95 percent of the CARD data available for calculating factors. The factors are ratios of percent recovery values at the 97.5 and 2.5 percentiles. The ratios generally show a consistent pattern.

An attempt to "convert" a biased value to its true concentration is not recommended because the CARD data do not differentiate and quantify individual sources of variation. The factors are applied as "safety factors" to ensure that biased data can be used to meet HRS criteria for determining an observed release. Dividing a high bias value by a factor effectively deflates it from the high end of the range to the low end (low bias value). Multiplying a low bias value by the factor effectively inflates it to a high bias value. Use of the ratio of percentiles is a "worst-case" assumption that the data are biased by the extent of the range of CARD data considered. The factors either inflate the values to the high end of the range, or deflate the data to the low end, and thus compensate for the apparent variability when comparing a high bias value to a low bias value (see Exhibit 1).

Factors have been selected for all analytes in the CLP Target Compound List (organic analytes) and Target Analyte List (inorganic analytes). Some organic factors were derived from matrix spike percent recoveries, and some from surrogate percent recoveries, depending on availability of data. When both matrix spike and surrogate data were available for the same compound, the larger value (representing more extreme high and low percent recoveries) was used. Laboratory control samples were used to calculate some of the inorganic factors. A default factor of 10 was used for analytes when percent recovery data were unavailable.

Application of the Factors: Exhibit 1 shows how to apply the factors to "J" qualified data. High bias background data, low bias release data, and unbiased data may be used at their reported concentrations. Multiply low bias background sample data by the analyte-specific factor to bring them to their new value. The new background value effectively becomes a high bias value that may be used to determine an observed release. Divide high bias release sample data by the analyte-specific factor to bring them to their new value. The new release sample value effectively becomes a low bias result that may be used

Exhibit 1: Use of Factors for J-Qualified Data		
Type of Sample	Type of Bias	Action Required
Background Sample	No Bias	None: Use concentration without factor
	Low Bias	Multiply concentration by factor
	High Bias	None: Use concentration without factor
	Unknown Bias	Multiply concentration by factor
Release Sample	No Bias	None: Use concentration without factor
	Low Bias	None: Use concentration without factor
	High Bias	Divide concentration by factor
	Unknown Bias	Divide concentration by factor

to determine an observed release. *Note: Adjusted release and background values must still meet HRS criteria (e.g., release concentration must be at least three times background level) to determine an observed release.*

Examples Using Trichloroethene in Soil:

1. *Release sample data biased low, background sample data biased high.*

Release sample value: 30 F/kg (J) *low bias*
Background sample value: 10 F/kg (J) *high bias*

In this instance, the direction of the bias indicates that the release sample concentration exceeds background by more than three times, so an observed release is established (provided all other HRS criteria are met). Use of the factors is not needed.

2. *Release sample data unbiased, background sample data biased low.*

Release sample value: 30 F/kg *no bias*
Background sample value: 10 F/kg (J) *low bias*

To use the data to establish an observed release, multiply the background sample value by factor given for trichloroethene (1.8). No factor is needed for the release sample.

New background sample value:
(10 F/kg) x (1.8) = 18 F/kg (J) *high bias*

The release sample concentration does not exceed the new background level by a factor of three, so an observed release is not established.

3. *Release sample data biased high, background sample data unbiased.*

Release sample value: 75 F/kg (J) high bias
Background sample value: 15 F/kg *no bias*

To use the data to establish an observed release, divide the release sample value by the factor for trichloroethene (1.8). No factor is needed for the background sample.

New release sample value:
(75 F/kg) ÷ (1.8) = 42 F/kg (J) *low bias*

The new release sample concentration does not exceed background concentration by a factor of three, so an observed release is not established.

4. *Release sample data biased high, background sample data biased low.*

Release sample value: 100 F/kg (J) *high bias*
Background sample value: 10 F/kg (J) *low bias*

To use the data to establish an observed release, divide the release sample value and multiply the background sample value by the factor given for trichloroethene in soil (1.8).

New release sample value:
(100 F/kg) ÷ (1.8) = 56 F/kg (J) *low bias*

New background sample value:
(10 F/kg) x (1.8) = 18 F/kg (J) *high bias*

The new release sample concentration is three times the new background concentration, so an observed release is established, provided all other HRS criteria are met.

Documentation Requirements for Use of Qualified Data: When using "J"-qualified data to determine an observed release, include the "J"-qualifier commentary from the data validation report in the HRS package. This step will ensure that the direction of bias is documented.

Use of Other Factors: EPA Regions may substitute higher factor values other than the ones in this fact sheet on a case-by-case basis when technically justified. For example; other factors may be applied to conform with site-specific Data Quality Objectives (DQOs) or with Regional Standard Operating Procedures (SOPs).[10]

Detection Limit Restrictions: Factors may only be applied to "J" data with concentrations above the CLP Contract Required Quantitation Limit (CRQL) or Contract Required Detection Limit (CRDL). "J"-qualified data with concentrations below CLP detection limits cannot be used to document an observed release.

Use of "UP"-Qualified Data

A combination of the "U" and "J" qualifiers indicates that the reported value may not accurately represent the concentration necessary to detect the analyte in the sample. Under limited conditions, "UJ" data can be used to represent background when determining observed release. These conditions include instances when there is confidence that the background concentration has not been detected and the sample measurement that establishes the observed release equals or exceeds the SQL or other appropriate detection limit. This reasoning is based on the presence of a high bias in the background sample. Thus, UJ data can be used only when all of the following conditions apply.

- The "UJ" value applies to the background sample and represents the detection limit,
- The "UJ" value is biased high, and
- The release sample concentration exceeds the SQL (or applicable detection limit) and is unbiased or biased low.

Summary

Data validation checks the usability of analytical data and identifies certain errors (bias). "J"-qualified data identify that analytes are present, but the reported values represent estimated concentrations associated with bias. Low bias release data and high bias background data may be used at the reported values. High bias release data and low bias background data may not be used at their reported concentrations because they do not establish an observed release with certainty. Application of factors introduced in this fact sheet compensate for this uncertainty, and enable "J" data to be used to determine an observed release.

Table 1: Factors for Volatile Organic Analytes				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
1,1,1-TRICHLOROETHANE	–	10.0	–	10.0
1,1,2,2-TETRACHLOROETHANE	11144	1.5	9180	1.2
1,1,2-TRICHLOROETHANE	–	10.0	–	10.0
1,1-DICHLOROETHANE	11144	1.4	9179	1.3
1,1-DICHLOROETHANE	2064	2.4	1484	2.0
1,2-DICHLOROETHANE	11144	1.4	9179	1.3
1,2-DICHLOROETHANE (TOTAL)	11144	1.4	9179	1.3
1,2-DICHLOROETHANE	–	10.0	–	10.0
2-BUTANONE	11144	1.4	9179	1.3
2-HEXANONE	11144	1.5	9180	1.2
4-METHYL-2-PENTANONE	11144	1.5	9180	1.2
ACETONE	11144	1.4	9179	1.3
BENZENE	2060	1.7	1482	1.5
BROMODICHLOROMETHANE	–	10.0	–	10.0
BROMOFORM	–	10.0	–	10.0
BROMOMETHANE	11144	1.4	9179	1.3
CARBON DISULFIDE	11144	1.4	9179	1.3

Table 1: Factors for Volatile Organic Analytes (continued)				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
CARBON TETRACHLORIDE	–	10.0	–	10.0
CHLOROBENZENE	2058	1.6	1480	1.4
CHLOROETHANE	11144	1.4	9179	1.3
CHLOROFORM	11144	1.4	9179	1.3
CHLOROMETHANE	11144	14	9179	1.3
CIS-1,3-DICHLOROPROPENE	–	10.0	–	10.0
DIBROMOCHLOROMETHANE	–	10.0	–	10.0
ETHYLBENZENE	11144	1.5	9180	1.2
METHYLENE CHLORIDE	11144	1.4	9179	1.3
STYRENE	11144	1.5	9180	1.3
TETRACHLOROETHENE	11144	1.5	9180	1.2
TOLUENE	2029	2.0	1468	1.4
TRANS-1,3-DICHLOROPROPENE	–	10.0	–	10.0
TRICHLOROETHENE	2046	1.8	1452	1.5
VINYL CHLORIDE	11144	1.4	9179	1.3
XYLENE(TOTAL)	11144	1.5	9180	1.2

Table 2: Factors for Semivolatile Organic Analytes				
SEMIVOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
1,2,4-TRICHLOROBENZENE	1978	3.5	1375	2.9
1,2-DICHLOROBENZENE	11899	3.8	7951	4.0
1,3-DICHLOROBENZENE	11899	3.8	7951	4.0
1,4-DICHLOROBENZENE	1980	3.8	1373	3.0
2,2'-OXYBIS(1-CHLOROPROPANE)	11899	3.8	7951	4.0
2,4,5-TRICHLOROPHENOL	11889	8.9	7952	3.6
2,4,6-TRICHLOROPHENOL	11889	8.9	7952	3.6
2,4-DICHLOROPHENOL	11896	4.0	7949	2.5
2,4-DIMETHYLPHENOL	11896	4.0	7949	2.5
2,4-DINITROPHENOL	11889	8.9	7952	3.6
2,4-DINITROTOLUENE	1979	3.4	1375	2.6
2,6-DINITROTOLUENE	11889	8.9	7952	3.6
2-CLORONAPHTHALENE	11889	8.9	7952	3.6
2-CHLOROPHENOL	1930	3.2	1376	2.9
2-METHYLNAPHTHALENE	11896	4.0	7949	2.5
2-METHYLPHENOL	11899	3.8	7951	4.0
2-NITROANILINE	11889	8.9	7952	3.6
2-NITROPHENOL	11896	4.0	7949	2.5
3,3'-DICHLOROBENZIDINE	11898	4.3	7951	6.0
3-NITROANILINE	–	10.0	–	10.0
4,6-DINITRO-2-METHYLPHENOL	–	10.0	–	10.0
4-BROMOPHENYL-PHENYL ETHER	–	10.0	–	10.0
4-CHLORO-3-METHYLPHENOL	1927	3.6	1375	3.5
4-CHLOROANILINE	11896	4.0	7949	2.5
4-CHLOROPHENYL-PHENYL ETHER	11899	8.9	7952	3.6
4-METHYLPHENOL	11899	3.8	7951	4.0

Table 2: Factors for Semivolatile Organic Analytes (continued)				
SEMIVOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
4-NITROANILINE	11889	8.9	7952	3.6
4-NITROPHENOL	1905	4.8	1368	4.5
ACENAPHTHENE	1965	3.1	1361	3.0
ACENAPHTYLENE	11889	8.9	7952	3.6
ANTHRACENE	–	10.0	–	10.0
BENEZO(A)ANTHRACENE	11898	4.3	7951	6.0
BENEZO(A)PYRENE	–	10.0	–	10.0
BENEZO(B)FLUORANTHENE	–	10.0	–	10.0
BENZO(G,H,I)PERYLENE	–	10.0	–	10.0
BENZO(K)FLUORANTHENE	–	10.0	–	10.0
BIS(2-CHLOROETHOXY)METHANE	11896	4.0	7949	2.5
BIS(2-CHLOROETHY)ETHER	11899	3.8	7951	4.0
BIS(2-ETHYLHEXYL)PHTHALATE	11898	4.3	7951	6.0
BUTYLBENZYLPHTHALATE	11898	4.3	7951	6.0
CARBAZOLE	–	10.0	–	10.0
CHRYSENE	11898	4.3	7951	6.0
DI-N-BUTYLPHTHALATE	–	10.0	–	10.0
DI-N-OCTYLPHTHALATE	–	10.0	–	10.0
DIBENZ(A,H)ANTHRACENE	11889	8.9	7952	3.6
DIBENZOFURAN	11889	8.9	7952	3.6
DIETHYLPHTHALATE	11889	8.9	7952	3.6
DIMETHYLPHTHALATE	11889	8.9	7952	3.6
FLUORANTHENE	–	10.0	–	10.0
FLUORENE	11889	8.9	7952	3.6
HEXACHLOROBENZENE	–	10.0	–	10.0
HEXACHLOROBUTADIENE	11896	4.0	7949	2.5
HEXACHLOROCYCLOPENTADIENE	11889	8.9	7952	3.6

Table 2: Factors for Semivolatile Organic Analytes (continued)				
SEMIVOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
HEXACHLOROETHANE	11899	3.8	7951	4.0
4-NITROPHENOLINDENO(1,2,3-CD)PYRENE	–	10.0	–	10.0
ISOPHORONE	11896	4.0	7949	2.5
N-NITROSO-DI-N-PROPYLAMINE	1966	3.7	1345	3.7
N-NITROSODIPHENYLAMINE(1)	–	10.0	–	10.0
NAPHTHALENE	11896	4.0	7949	2.5
NITROBENZENE	11896	4.0	7949	2.5
PENTACHLOROPHENOL	1895	18.8	1359	3.7
PHENANTHRENE	–	10.0	–	10.0
PHENOL	1924	3.2	1368	3.5
PYRENE	1901	8.3	1369	4.9

Table 3: Factors for Pesticide/PCB Analytes				
PESTICIDE/PCB ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
4,4'-DDD	–	10.0	–	10.0
4,4'-DDE	–	10.0	–	10.0
4,4'-DDT	1801	7.4	1353	4.6
ALDRIN	1870	7.9	1350	4.8
ALPHA-BHC	–	10.0	–	10.0
ALPHA-CHLORDANE	–	10.0	–	10.0
AROCLOR-1016	–	10.0	23305	8.7
AROCLOR-1221	–	10.0	23305	8.7
AROCLOR-1232	–	10.0	23305	8.7
AROCLOR-1242	–	10.0	23305	8.7
AROCLOR-1248	–	10.0	23305	8.7
AROCLOR-1254	–	10.0	23305	8.7
AROCLOR-1260	–	10.0	–	10.0
BETA-BHC	–	10.0	–	10.0
DELTA-BHC	–	10.0	–	10.0
DIELDRIN	1886	6.2	1350	2.8

Table 3: Factors for Pesticide/PCB Analytes (continued)				
PESTICIDE/PCB ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
ENDOSULFAN 1	–	10.0	–	10.0
ENDOSULFAN 11	–	10.0	–	10.0
ENDOSULFAN SULFATE	–	10.0	–	10.0
ENDRIN	1866	8.5	1348	3.4
ENDRIN ALDEHYDE	–	10.0	–	10.0
ENDRIN KETONE	–	10.0	–	10.0
GAMMA-BHC (LINDANE)	1872	4.5	1350	3.1
GAMMA-CHLORDANE	–	10.0	–	10.0
HEPTACHLOR	1877	4.5	1351	3.6
HEPTACHLOR EPOXIDE	–	10.0	–	10.0
METHOXYCHLOR	–	10.0	–	10.0
TOXAPHENE	–	10.0	–	10.0

Table 4: Factors for Inorganic Analytes				
INORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
ALUMINUM	1147	1.5	1686	1.2
ANTIMONY	1153	1.8	1688	1.2
ARSENIC	1208	1.6	1701	1.2
BARIUM	1149	3.3	1686	1.1
BERYLLIUM	1150	1.2	1686	1.2
CADMIUM	1148	1.3	1685	1.2
CALCIUM	1163	1.2	1685	1.1
CHROMIUM	1148	1.2	1686	1.2
COBALT	1153	1.2	1685	1.2
COPPER	1154	1.1	1683	1.2
CYANIDE	884	1.4	–	10.0
IRON	1149	1.2	1687	1.2
LEAD	1331	1.3	1727	1.2
MAGNESIUM	1143	1.2	1686	1.1
MANGANESE	1151	1.2	1685	1.2
MERCURY	1563	1.7	–	10.0
NICKEL	1150	1.2	1685	1.2
POTASSIUM	–	10.0	–	10.0
SELENIUM	1190	2.3	1695	1.3
SILVER	1152	1.6	1684	1.3
SODIUM	–	10.0	–	10.0
THALLIUM	1197	1.7	1691	1.2
VANADIUM	1152	1.2	1685	1.1
ZINC	1154	1.3	1689	1.2

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